DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 7 1986

Re: Cefotan
Docket No. 86E-0098

Charles E. Van Horn, Esq.
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent extension for U.S. Patent 4,263,432 filed by Yamanouchi Pharmaceutical Co., Ltd. under 35 U.S.C. 156. The human drug product claimed by the patent is Cefotan, new drug application (NDA) number 50-588.

In the April 8, 1986 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). That notice provided that on or before October 6, 1986, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice regarding Cefotan has expired, and FDA has received no such petition. FDA, therefore, considers its determination of the regulatory review period for Cefotan to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Frank J. Simonski

for Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Rosemary M. Miano, Esq.
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